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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
01035.0025-00000

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Application Number	Filed
09/746,144	December 21, 2000

First Named Inventor: Wayne E. CORNISH

Art Unit	Examiner
3736	Jonathan M. Foreman

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.

☒ attorney or agent of record.
Registration number 45,284.

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

/Louis Troilo/
Signature

Louis Troilo
Typed or printed name

(202) 408-6020
Telephone number

September 29, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PATENT
Customer No. 72,207
Attorney Docket No. 01035.0025-00000

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Wayne E. CORNISH et al.	)	Group Art Unit: 3736
	)	
Application No.: 09/746,144	)	Examiner: Jonathan M. Foreman
	)	
Filed: December 21, 2000	)	
	)	
For: SUPERELASTIC GUIDEWIRE WITH LOCALLY ALTERED PROPERTIES	)	Confirmation No.: 2421

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

In reply to the final Office Action mailed May 30, 2008, and further to the Notice of Appeal filed herewith, Applicants respectfully request review of the outstanding rejection in view of the following remarks. Claims 7 and 20-26 are pending and subject to examination.

I. REJECTIONS UNDER 35 U.S.C. § 103

A. Rejections over Anderson in view of Stevens

Claims 7 and 20-26 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Anderson (U.S. Patent No. 6,325,766) in view of Stevens (U.S. Patent No. 5,722,981). Final Office Action at 2. The Examiner asserts that Anderson discloses "an elongated medical device having a superelastic member (12) having a first set of properties and an adjacent second section (14) having a second set of properties." *Id.* The Examiner acknowledges, however, that Anderson "fails to disclose the alloy including an easily diffusible element consisting of oxygen or hydrogen." *Id.* To remedy this deficiency, the Examiner relies on Stevens, alleging that "Stevens teaches a nickel-titanium alloy having a reduced superelasticity which includes oxygen or hydrogen." *Id.* The Examiner concludes that "it would

have been obvious to one of ordinary skill in the art at the time of the invention to substitute one alloy for the other to achieve the predictable results of allowing the medical device to have a pre-formed shape, be stressed into another shape, and then return to its pre-formed shape." *Id.* Applicants respectfully disagree and traverse this rejection for at least the following reasons.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. M.P.E.P. § 2142. In *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q. 2d 1385 (2007), the Supreme Court confirmed that the "framework for applying the statutory language of §103" was still based on its landmark decision in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). As detailed below, it is evident that the Examiner has not established a *prima facie* case of obviousness even in light of the *KSR* decision.

First, neither Anderson nor Stevens discloses treating a superelastic member in an elongated device with an easily diffusible element selected from oxygen, nitrogen, and hydrogen, as claimed. As the Examiner acknowledges, Anderson does not disclose the alloy including an easily diffusible element consisting of oxygen or hydrogen." Office Action at 2. If fact, the alloy used to construct the device could be either superelastic NiTi containing carbon, *or* stainless steel, or "cobalt based MP35N and L605, and Elgiloy." Anderson, column 2, lines 13-18, and 38-62. To the extent that Anderson teaches anything related to hydrogen, oxygen, or nitrogen, it merely is to show that such elements can exists in small amounts in alloys. Anderson does not disclose treating any alloy with hydrogen, oxygen, or nitrogen, and certainly not to affect the alloy's properties.

Stevens is even more deficient in that it does not mention hydrogen, oxygen, or nitrogen. No where in Stevens does it disclose "reduced superelasticity" due to addition of oxygen or hydrogen in the alloy. Rather, this reference described using commercially available alloys. *See* Stevens, col. 3, lines 42-49, teaching that its preferred material is available from Shape Memory Applications, Inc. of Sunnyvale, Calif. Thus, Stevens clearly does not remedy the deficiencies of Anderson.

Second, none of the cited references teach treating a specific section of the medical device to change the properties of that particular section. Although Stevens discloses a NiTi alloy having other elements, Stevens does not correct Anderson's failure to teach an elongated member having two adjacent superelastic sections, much less two adjacent superelastic portions wherein one portion exhibits altered properties as a result of being treated with an easily diffusible element selected from oxygen, nitrogen, and hydrogen, as claimed. Thus, even if, *arguendo*, one of ordinary skill in the art would have been motivated to combine Anderson with Stevens in the manner suggested by the Examiner, the resulting combination would still fail to teach or suggest each and every element of at least claim 7.

The Examiner argues that "the claimed invention is a product by process type of claim. As such, the claimed invention is not limited to the manipulations of the recited steps, only the structure implied by the steps. MPEP 2113." Final Office Action at 3-4. Even if the Examiner was correct regarding the claims being product-by-process, which characterization Applicants do not agree with, the structure implied by the claims are clearly distinct from the cited prior art. It is well-known that "[t]he structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structure characteristics to the final product." MPEP 2113.

Claim 7 recites, in relevant part, "a superelastic member having a first section with a first set of properties and an adjacent second section having a second set of properties which have been altered from the first set of properties by treating the second section with an easily diffusible element." The alleged process limitations of "treating" clearly impart distinctive characteristics to the final product. For example, in the resulting superelastic member, one of the differences in the compositions of the first and the second sections is that the second section has all elements that the first section has, in addition to a higher concentration of the claimed easily diffusible element.

In contrast, Anderson uses "either superelastic NiTi containing carbon, or stainless steel, or "cobalt based MP35N and L605, and Elgiloy." Anderson, column 2, lines 13-18, and 38-62. And Stevens discloses a preferred material containing 55.7% Ni, 43.9% Ti, 0.20% Cr, 0.033% C, 0.069% O, 0.0019% H, and 0.0961 other elements. Stevens, column 3, lines 42-46. Nothing in these references remotely suggest a superelastic element, as claimed.

Therefore, Anderson and Stevens, individually or in combination, do not teach a medical device having two sections as claimed, and certainly not with the different properties. These references also do not provide a motivation or suggestion to treat a section of a medical device of the claimed invention to alter its properties. Since treating a section of a medical device with a diffusible element was never mentioned in the references, one of ordinary skill in the art at the time of invention would not have thought of such an unique way of obtaining a medical device, much less having an expectation of the success. Applicants respectfully request withdrawal of the rejection based on the above reference.

B. Rejections over Yamauchi in view of Abel

The Examiner also rejects claims 7 and 22-26 under 35 U.S.C. § 103(a) as unpatentable over Yamauchi (JP04187159A) in view of Abel (U.S. Patent No. 6,428,317). Office Action at 3. The Examiner alleges that Yamauchi discloses the claim limitations, including "treating a second section [of the superelastic member] with an easily diffusible element," but admits that this reference fails to teach "the easily diffusible element being selected from the group consisting of oxygen, hydrogen and nitrogen." *Id.* Abel, the Examiner maintains, "teaches that heat treatments and/or the addition of trace elements such as oxygen (O) and nitrogen (N) to nickel-titanium alloys can be very significant effects on desired superelastic properties and performance of the material." *Id.* at 3. Applicants disagree for at least the following reasons.

At the outset, Yamauchi teaches heat-treating the base and/or apex part of a catheter guide wire. See Yamauchi, Abstract. Nowhere in Yamauchi does it disclose treating the guide wire with an easily diffusible element. Abel, on the other hand, does not teach diffusing hydrogen, oxygen, or nitrogen into a

nitinol alloy after the alloy has been formed. Rather, it merely describes alloys comprising trace amounts of such elements that result from their fabrication, not treating such alloys after they are produced. Thus, none of Yamauchi and Anderson disclose treating a superelastic member of a medical device with hydrogen, oxygen, or nitrogen, and certainly not to affect properties of different sections of that superelastic member.

Therefore, one of ordinary skill in the art, knowing that adding trace elements to the alloy alters the properties of the alloy by reading Abel, and knowing that heat treatment alters the properties of a guide wire by reading Yamauchi, still can not arrive at the specific medical device as claimed.

Furthermore, Abel is vague on what "significant effects" on what "desired superelastic properties and performance of the materials." See Abel at 10-14. Hence there is no indication, either in Yamauchi or in Abel, as to why NiTi treated with oxygen and/or hydrogen would be beneficially used in Yamauchi's device.

For at least the foregoing reasons, Applicants submit that the Examiner has not established a prima facie case of obviousness in rejecting the claimed invention. Applicants respectfully request the rejections withdrawn.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

/Louis Troilo/

Dated: September 29, 2008 By:_____

Louis M. Troilo
Reg. No. 45,284